

**UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF DELAWARE**

ABBOTT LABORATORIES, an Illinois  
corporation,

Plaintiff,

v.

BANNER PHARMACAPS, INC., a Delaware  
corporation,

Defendant.

Civil Action No. 07-CV-00754-GMS

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**JOINT STATUS REPORT**

In response to this Court's August 1, 2008 Order, Plaintiff Abbott Laboratories ("Abbott") and Defendant Banner Pharmacaps, Inc. ("Banner"), hereby provide the Court with the following joint report on the status of all agenda items for the upcoming September 10, 2008 conference.

**1. Jurisdiction and Service**

**A. Personal Jurisdiction**

Abbott filed this patent infringement action pursuant to the federal Hatch-Waxman Act (35 U.S.C. § 271(e)(2)) against Banner on November 21, 2007. (*See* Complaint (D.I. 1).) Banner waived service. (*See* Waiver of Service (D.I. 6).) There are no additional parties remaining to be served, and both Abbott and Banner are subject to personal jurisdiction in this District for the purposes of this suit.

**B. Subject Matter Jurisdiction**

Abbott's patents-in-suit expired on January 29, 2008, and Abbott accordingly moved for voluntary dismissal of its infringement claims with prejudice. (*See* D.I. 18.) Banner agrees that Abbott's infringement claims may be dismissed with prejudice. (*See* D.I. 23.)

Banner has asserted two counterclaims: the first is for a “Declaratory Judgment of Non-Infringement of the ‘731 and ‘326 Patents,” and the second is for “Unfair Competition.” The parties dispute whether the Court has subject matter jurisdiction to adjudicate the first counterclaim.<sup>1</sup> Abbott has moved to dismiss that counterclaim pursuant to Fed. R. Civ. P. 12(b)(1). (*See* D.I. 21-22.) Banner has opposed that motion. (*See* D.I. 25.)

There are no other pending jurisdictional challenges.

## **2. Substance of the Action**

### *A. Abbott’s Position*

Abbott’s patent infringement claims against Banner arise under the federal Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and are based upon Banner’s submission to the FDA of New Drug Application No. 22-152 – which sought approval of a purported generic version of Abbott’s popular Depakote<sup>®</sup> product (widely prescribed in the treatment of convulsive disorders, bipolar disorder, and migraine headaches). Abbott owns two patents (the ‘731 and ‘326 patents) that cover the active ingredient in Depakote<sup>®</sup> and that are listed in the FDA’s Orange Book – a compendium that includes all FDA-approved products and their associated patents – in conjunction with that product. In October 2007, after Banner had submitted the NDA, it gave a statutorily-required notice to Abbott about that submission. *See* 21 U.S.C. § 355(b)(3). Importantly, Banner informed Abbott that the NDA included a “Paragraph IV certification” directed to Abbott’s patents, by which Banner averred to FDA that its proposed generic product would not infringe Abbott’s ‘731 or ‘326 patents and should thus be approved for marketing prior to the patents’ expiry.

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<sup>1</sup> Abbott does not challenge the Court’s subject matter jurisdiction over the second counterclaim, but has moved to dismiss that counterclaim as well for failure to state a claim upon which relief may be granted. (*See* D.I. 11-12.) Banner has opposed that motion. (*See* D.I. 15.)

Under the Hatch-Waxman Act, this submission by Banner of an NDA containing a Paragraph IV certification challenging Abbott's patents was, by itself, an act of patent infringement. *See* 35 U.S.C. § 271(e)(2); *see also* *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007) ("The very act of submitting an ANDA [with a Paragraph IV certification] is an act of infringement."); *Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 429 (D. Del. 2007) (Sleet, J.) (this Court noted that Apotex's filing of an ANDA with a Paragraph IV certification was, by statute, an act of infringement). According to the statute, Abbott had 45 days from its receipt of the October 2007 notice from Banner to file suit and to protect its patent rights. *See* 21 U.S.C. § 355(c)(3)(C). Abbott filed this timely action against Banner on November 21, 2007. By operation of statute, Abbott's filing automatically triggered a 30-month stay of FDA approval of Banner's NDA. *See* 21 C.F.R. § 314.107(b)(3)(i)(A).

Abbott's '731 and '326 patents expired on January 29, 2008, and Banner's product has been finally approved for marketing by FDA. Thus, as set forth fully in other briefing before the Court, Abbott believes that this entire matter is moot and should be dismissed, with prejudice. (*See* D.I. 18.) Banner has asserted two counterclaims in this matter. The first seeks a declaratory judgment that Banner's NDA product does not infringe Abbott's patents. As noted in its motion to dismiss, Abbott respectfully submits that this counterclaim no longer presents a live case or controversy, given that the patents have now expired. (*See* D.I. 21-22.) The second counterclaim is fashioned as one for "Unfair Competition" and is grounded on the notion that Abbott had an insufficient basis to file this case. Because Banner's submission of the NDA was, as a matter of law, an act of patent infringement, however, Abbott had ample justification to initiate this lawsuit. *See Teva*, 482 F.3d at 1342. Banner's second counterclaim, like the first, is deficient as a matter of law and should be dismissed, with prejudice. (*See* D.I. 11-12, 17.)

*B. Banner's Position*

Banner disagrees with Abbott's arguments as to the substance of the action. Banner agrees that Abbott purported to file the present patent infringement against Banner under the federal Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and that Banner had submitted to the FDA a New Drug Application No. 22-152. However, it is incorrect that Banner sought approval of a generic version of Abbott's Depakote® product.

Further, it is not correct that Banner "challenged Abbott's patents." Banner's NDA was explicitly directed solely to valproic acid, and Banner stated that the product did not infringe the Abbott patents where all the claims were restricted to an oligomer of 1:1 molar ratio of sodium valproate and valproic acid. Banner disagrees that, under the Hatch-Waxman Act, its submission of an NDA containing a Paragraph IV certification was, by itself, an act of patent infringement.

As set forth fully in other briefing before the Court, Banner rejects Abbott's contention that Abbott may file a frivolous patent infringement action solely to damage Banner by improperly delaying FDA approval of its product, and, after succeeding in harming Banner, have the Court dismiss the actions.

Banner has asserted two counterclaims in this matter. The first seeks a declaratory judgment that Banner's NDA product did not infringe the two Abbott patents. The second counterclaim is for "Unfair Competition" based on Abbott's filing of the action for ulterior unfair competitive purposes.

**3. Identification of Issues**

*A. Abbott's Position*

Abbott believes that the only issues genuinely in dispute at this time concern whether Banner's counterclaims should be dismissed, with prejudice.

*B. Banner's Position*

Banner asserts that the principal factual and legal issues genuinely in dispute are the following:

A. Whether Abbott's proposed NDA product directed solely to valproic acid infringed the two Abbott Patents upon which Abbott sued Banner, when all the Abbott patent claims were restricted to an oligomer of 1:1 molar ratio of sodium valproate and valproic acid.

B. Given Banner's NDA and the plain language of the Abbott claims, as defined above, what, if any basis, did Abbott have for suing Banner for the two patents in the suit.

C. The amount of any damages to which Banner is entitled, and/or whether the entry of other equitable relief is warranted.

D. Whether this case is exceptional within the meaning of 35 U.S.C. § 285, permitting the award of attorneys' fees.

**4. Narrowing of Issues**

The parties are agreed that Abbott's affirmative claims in this matter should be dismissed, leaving only a dispute as to Banner's two counterclaims. Abbott has moved to dismiss both counterclaims, and Banner has opposed. Depending upon the Court's resolution of these motions, the issues in this matter may be narrowed or eliminated.

**5. Requested Relief**

*A. Abbott's Position*

Given the expiry of the underlying patents, Abbott does not seek any affirmative relief for patent infringement. Because Banner's product was not approved by FDA, and thus was not actually sold to the public, until after Abbott's patents expired, there is no claim for money damages. At this point, the only relief Abbott seeks is the dismissal of this action, in its entirety, with prejudice.

*B. Banner's Position*

Banner's unfair competition counterclaim asserts that Abbott filed the Complaint with knowledge that its patent infringement claims were untenable because Banner's NDA was explicitly directed solely to valproic acid, and could not have included the patented subject matter of an oligomer with 1:1 molar ratio of sodium valproate and valproic acid as claimed in both Abbott patents. (D.I. 7 at 5-6.) The damages that Banner seeks under its counterclaim include Banner's costs, fees and disbursements as a result of the suit, in addition to the profits that Abbott obtained and Banner lost from Abbott's sham lawsuit.

**6 & 7. Amendment of Pleadings and Joinder of Parties**

*A. Abbott's Position*

Abbott believes that no further amendment of the pleadings (or joinder of additional parties) is necessary in this case.

*B. Banner's Position*

Banner proposes a date that is forty-five (45) days after the Court's final determinations of all currently-pending Motions by Abbott, by which pleadings can be amended and parties added.

**8. Discovery**

*A. Abbott's Position*

Abbott respectfully submits that no additional fact or expert discovery is warranted in this matter, because it should be dismissed. If, after reviewing the various pending motions to dismiss, the Court is inclined to allow some portion of this litigation to proceed, then Abbott submits that it would be prudent for the parties at that time to assess the scope of the case and to provide their respective positions about any necessary discovery.

*B. Banner's Position*

Discovery should proceed as normal, with discovery limited as provided by the default provisions in the Federal Rules of Civil Procedure. Banner proposes that the Parties will commence all discovery in time for fact discovery to be completed on or before March 31, 2009.

**9. Estimated Trial Length**

*A. Abbott's Position*

Abbott believes that the case should be dismissed, and that no trial will be necessary. If this Court denies one or more of Abbott's pending motions to dismiss, however, then Abbott will, in light of the nature of the Court's ruling, provide its position with respect to any appropriate trial length.

*B. Banner's Position*

Banner believes that the trial of this matter will last for less than one week.

**10. Jury Trial**

Abbott has not requested trial by jury on any matter in this case. Banner has requested trial by jury on all claims so triable. (*See* D.I. 7.)

**11. Settlement**

The parties have preliminarily discussed resolution of this matter, but were unable to reach agreement on acceptable terms. Neither party believes that settlement is likely at this time, or that negotiations would be facilitated by any formal ADR mechanism.

**12. Other Relevant Matters**

*A. Abbott's Position*

Abbott believes that, aside from the topics discussed in points 1-11 of this Report, there are no "other matters" to be discussed whose resolution would be "conducive to the just, speedy and inexpensive determination of this action." (Scheduling Order (D.I. 20) at 2.) In light of the

three pending motions to dismiss, Abbott respectfully suggests that any discussion of a schedule governing further actions in this case – particularly one that purports to include claim construction of expired patents – is inappropriate. For this reason, Abbott does not consent to any part of Banner's proposed schedule.

*B. Banner's Position*

Banner proposes the following the following additional scheduling terms:

A. Initial Disclosures pursuant to Federal Rule of Civil Procedure 26(a) will be provided on or before October 14, 2008.

B. The Parties exchange any proposed claim constructions by December 12, 2008. In the event that the parties can not agree on claim constructions, the parties shall file a final joint claim chart which shall include citations to intrinsic evidence on or before January 9, 2009. The Parties will exchange opening claim construction briefs on or before February 13, 2009 and answering claim construction briefs on or before March 6, 2009.

C. The Parties will serve opening expert reports on issues for which that party bears the burden of proof 45 days after the Court enters an Order construing disputed claim terms, or 45 days after the close of fact discovery if the Court is not required to construe claims; and responsive expert reports will be served 30 days after the opening reports. Any rebuttal reports may be served 15 days after the answering reports.

D. The Parties will submit any letter briefs seeking permission to file any summary judgment motions 10 days after the rebuttal expert reports are due, and answering letter briefs will be filed within 14 days thereafter, and reply letter briefs will be filed within 10 days thereafter.



E. Should the Court permit the filing of summary judgment motions, an opening brief and affidavits, if any, in support of the motion shall be served and filed within 14 days after the Court permits such motions, answering brief and affidavits shall be filed within 15 days after service of the opening brief, and reply brief shall be filed within 15 days after service of the answering brief;

F. Thirty (30) days before a joint pretrial order is due, each Party will forward a draft of a pretrial order to the other Parties; and

G. Opening briefs on all motions in limine shall be filed on or before six weeks prior to the Pretrial Conference. All answering briefs on all motions in limine shall be filed within 14 days from filing of the opening briefs. All reply briefs on all motions in limine shall be filed within 7 days from filing of the answering briefs.

**13. Statement of Conference**

The parties hereby state that they have conferred about each of the topics discussed in points 1-12 of this Report. The parties have not discussed the timing and events included on Banner's proposed schedule, however, because Abbott believes that a schedule should not be set at all in this case.

Dated: September 3, 2008

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that, on September 3, 2008, a true and correct copy of the foregoing document, entitled **Joint Status Report**, was served on the following persons via the following methods:

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